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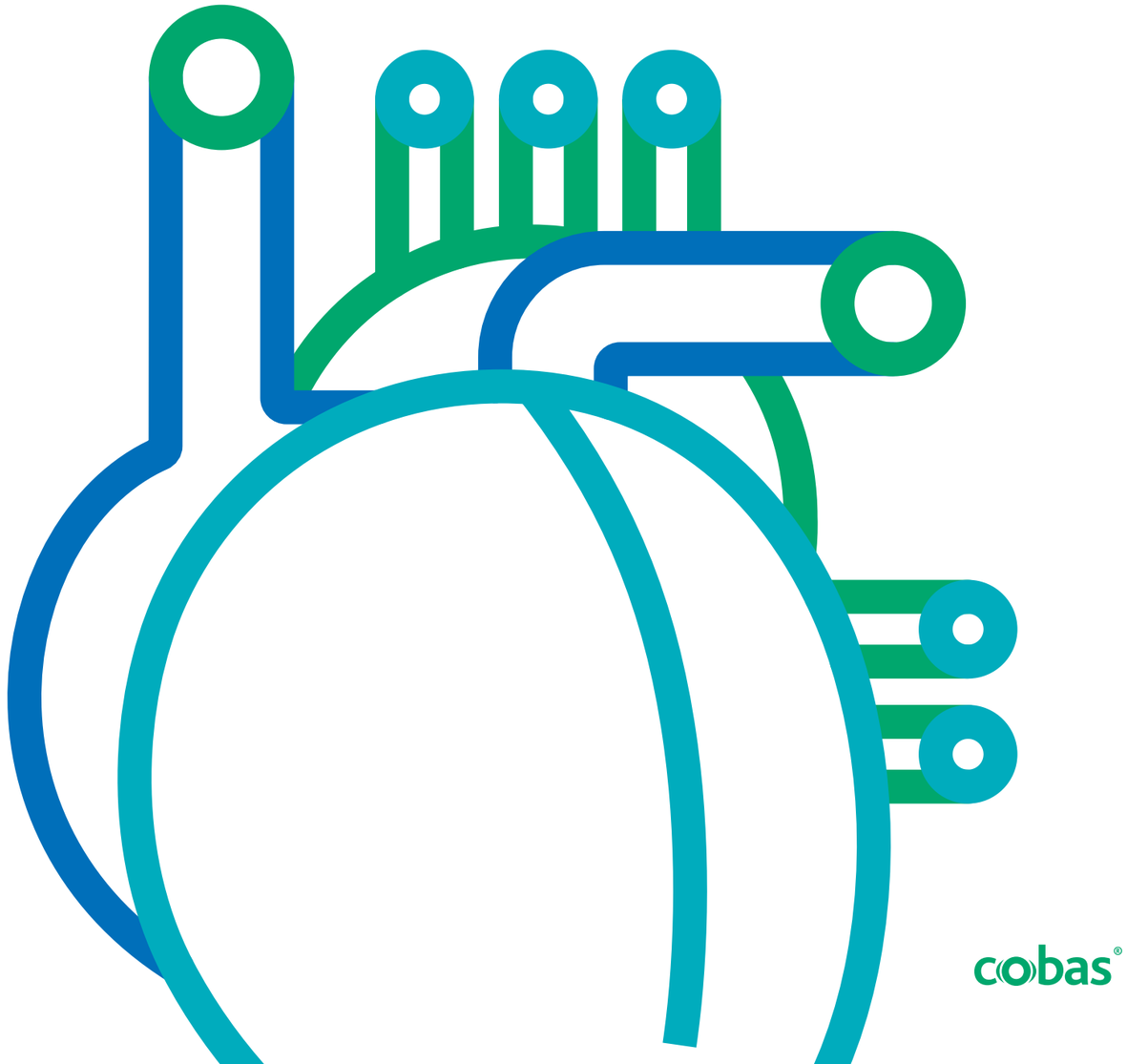
Introducing the cobas h 232 POC system

On the spot results to support efficient diagnosis and management of cardiovascular diseases[1,2]



cobas®

Introducing the cobas h 232 POC system

Fast results to support confident on-site decision making for cardiovascular patients[1,2]

Test multiple biomarkers

Confidently test for markers and make a differential diagnosis.[3-7]

D-Dimer
Rule out pulmonary embolism (PE) and deep vein thrombosis (DVT)[3,8]

NT-proBNP
Exclude heart failure (HF) and identify patients in need of further cardiac investigation[4,9]

Cardiac Troponin T
Early rule in acute myocardial infarction (AMI) and help identify patients with elevated mortality risk[5,10,11]

CK-MB
Aid in the diagnosis of AMI and detection of reinfarction[6,10]

Myoglobin
Support in the early diagnosis of AMI[7,12]

On the spot care & share: obtain results within minutes and share wirelessly with the multidisciplinary team

Fast results

Receive results in 8 – 12 minutes[2]
The time varies with the assay used

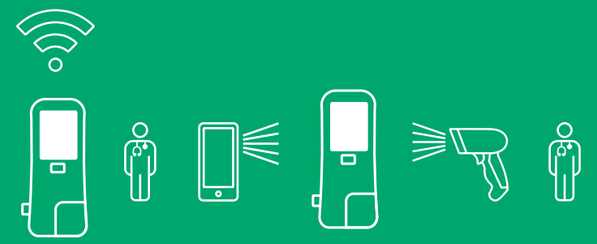
Portable design

Easy-to-use handheld system for use "on the go" in multiple locations[2]

General practitioner office | Ambulance | Emergency department

Share immediately

Share data with the multidisciplinary care team via WiFi or QR code for fast result transfer and fewer manual steps[2]



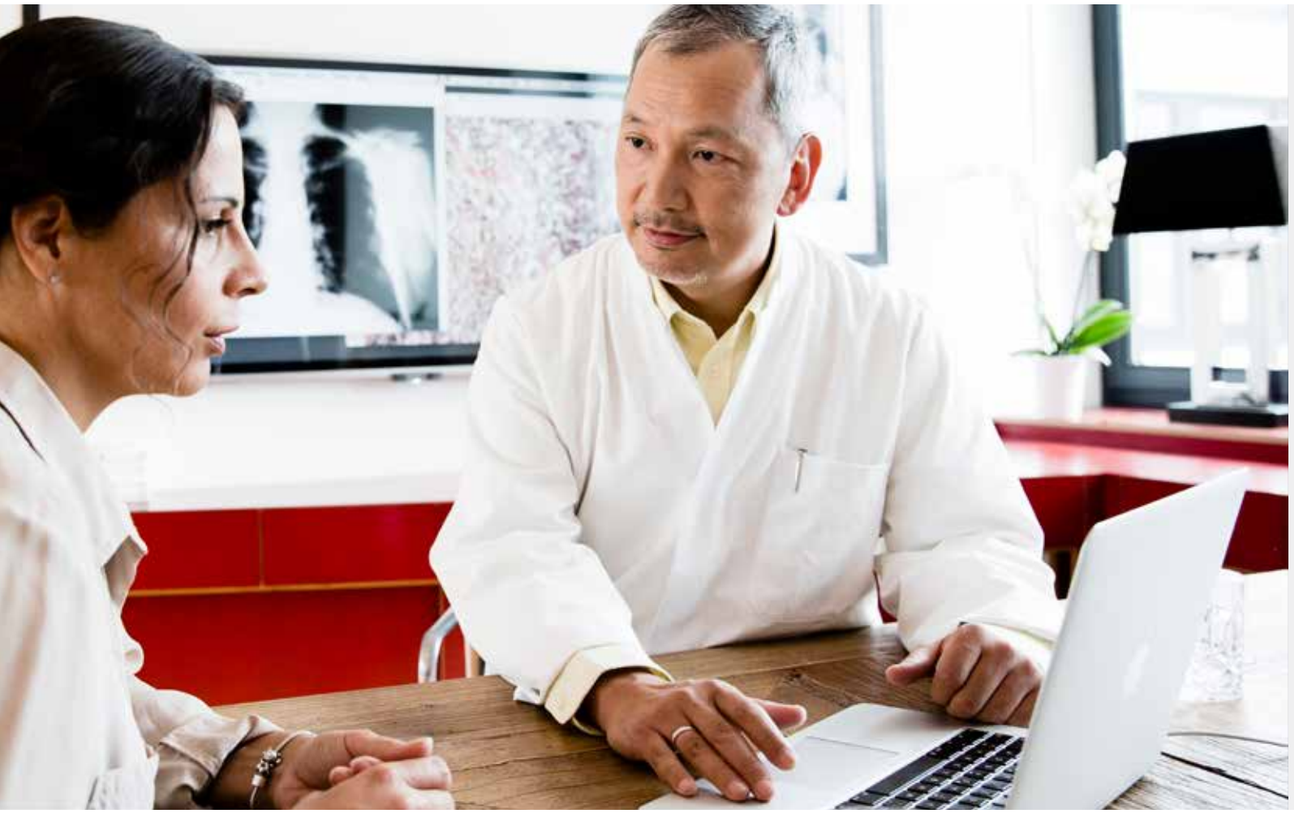
Enable confident diagnosis

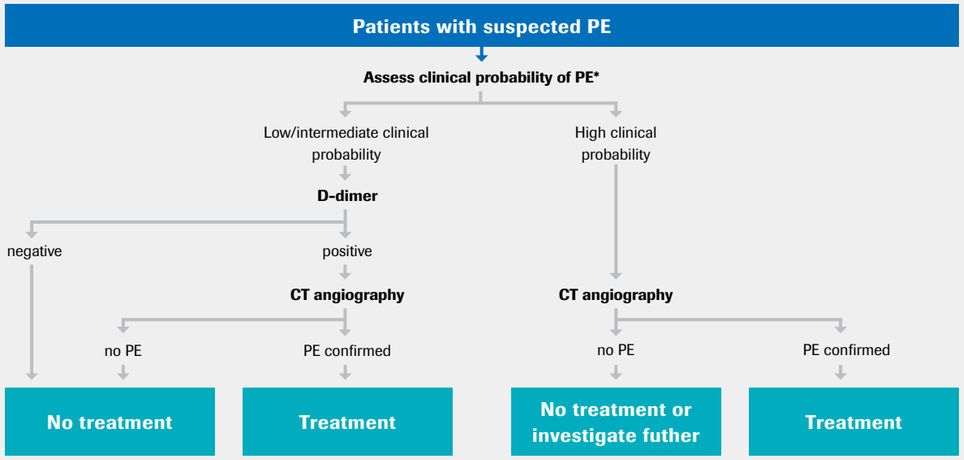
Be assured that POC and laboratory tests are standardized, so results and cut-offs can be easily compared across Roche **cobas** immunochemistry platforms and locations[1,13]

cobas h 232 POC system | 1 heparinized tube | immunochemistry platforms

D-Dimer with the cobas h 232 POC system

For exclusion of suspected Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT)[8]





CT = computer tomographic
* Clinical probability is determined by a clinical model as published in reference 8 looking at the clinical characteristics of DVT or PE.

D-Dimer cut-off[3]

< 0.5 µg/mL
Acute PE or DVT unlikely

≥ 0.5 µg/mL
CT angiography

Offering fast, portable, on-the-spot results to aid in the diagnosis of PE and DVT

Guideline recommended

ESC guidelines on the diagnosis and management of acute PE recommend D-Dimer testing on patients with low/ moderate clinical probability of PE.

The proposed diagnostic algorithm includes a D-dimer test used in conjunction with the clinical probability score.[8]

Rapid reliable exclusion test

- When used in conjunction with a low to moderate pre-test probability score, a negative D-Dimer test has shown to have 100 % negative predictive value[14]
- A positive D-Dimer test does not confirm the PE or DVT diagnosis. Further imaging diagnostic procedure is then required

Save time and costs

- Rule out PE/DVT in patients with low to moderate probability in less than 10 minutes[3]
- Avoid hospital admission for patients with negative D-Dimer results and low to moderate pre-test probability
- Reduce unnecessary imaging[15]

NT-proBNP with the cobas h 232 POC system

To support diagnosis and long-term management of Heart Failure (HF)[4,9,16]

Offering fast, portable, on-the-spot results to aid in the diagnosis and management of HF

Use as an initial diagnostic test

In association with clinical evaluation,* NT-proBNP can support decision-making in HF diagnosis in acute and non-acute settings.[9]

- Exclude HF and avoid unnecessary echocardiography[17-19]
- Identify patients with high probability of having HF and need further investigation[9]
- In primary care, identify patients who need referral to the specialist[17-19]

Use to monitor disease

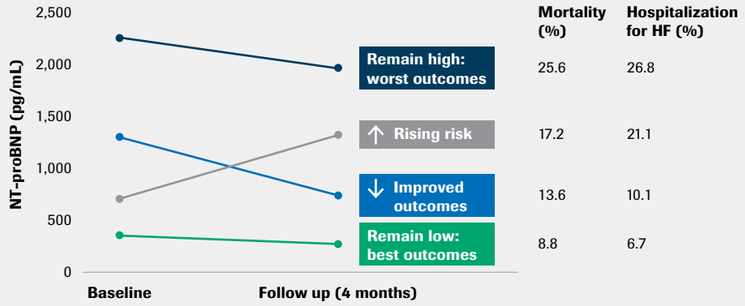
Changes in NT-proBNP levels provide important prognostic information to help identify patients at risk of hospitalization for HF and mortality.[9,22-26]

Monitoring NT-proBNP levels helps to manage HF well over the long term, regardless of symptoms or medication being taken, in particular angiotensin receptor-neprilysin inhibitors (ARNis).[27]

*Assessment of HF probability through patient history, physical examination and if possible electrocardiogram.

NT-proBNP cut-off levels (pg/mL)[9,20,21]

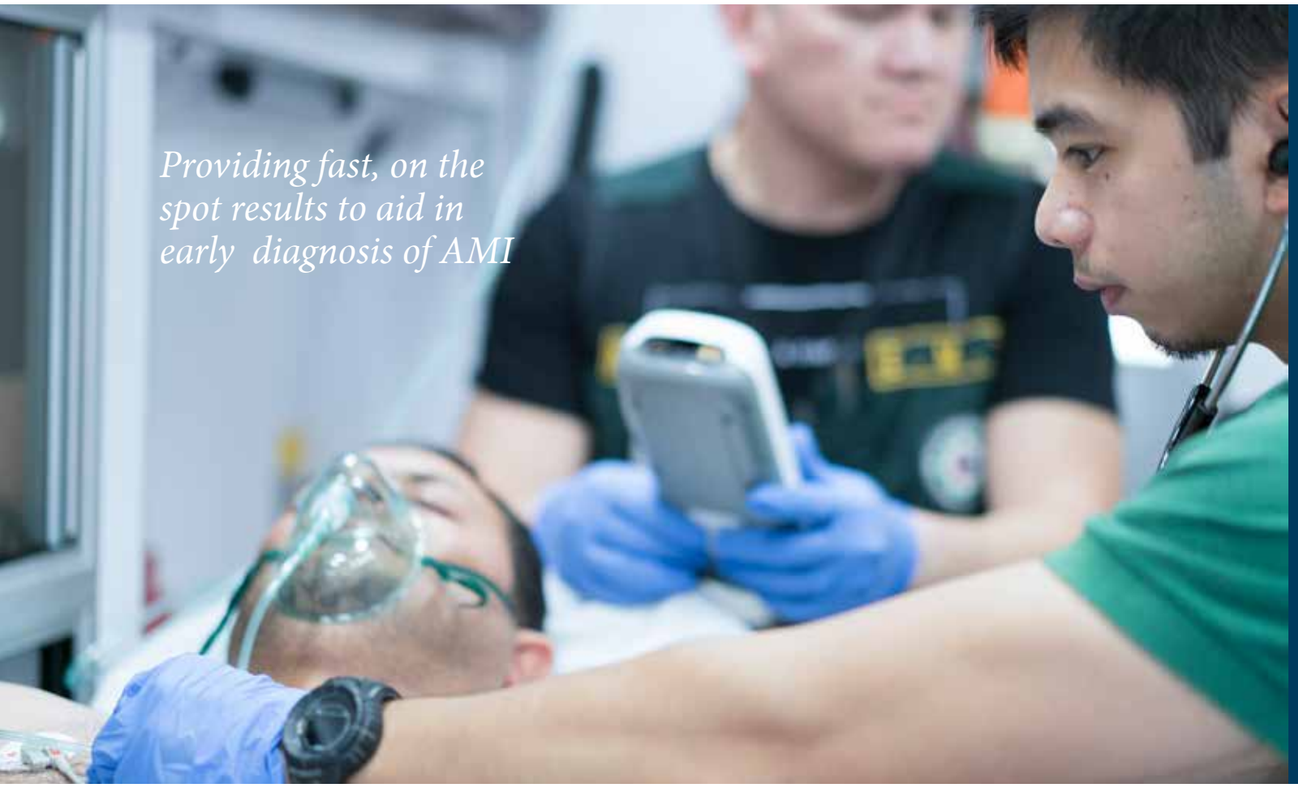
	Age	HF unlikely consider other diagnosis	HF less likely, diagnosis by imaging	HF likely, confirmation by imaging
Acute settings (e.g. emergency department)	<50 years old	<300	300 – 450	>450
	50 – 70 years old	<300	300 – 900	>900
	>75 years old	<300	300 – 1,800	>1,800
Non-acute settings (e.g. primary care, ambulance)	All ages	<125		>125

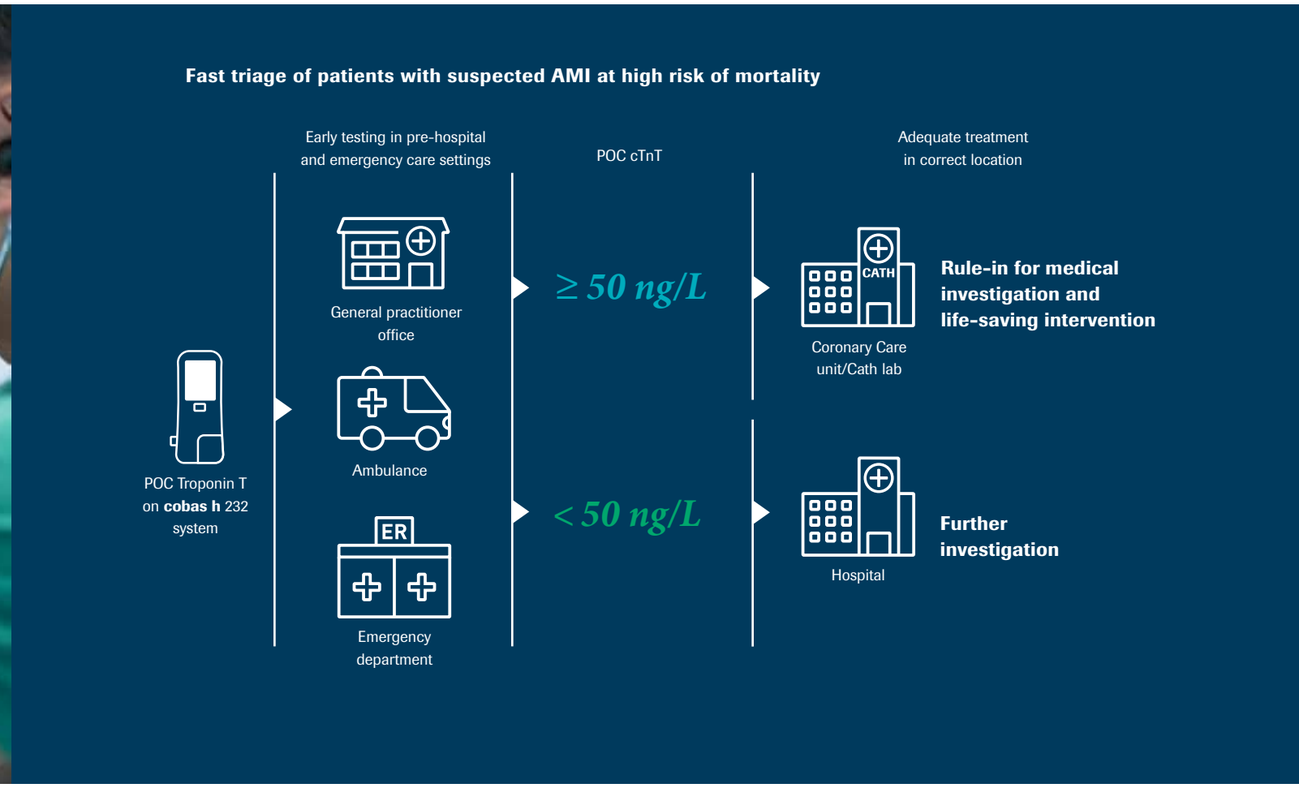


Graph adapted from Masson et al. (2008) and Januzzi et al. (2012)[22,26]

Troponin T
with the cobas h 232 POC system

For faster triaging of patients with suspected Acute Myocardial Infarction (AMI)[5,11]



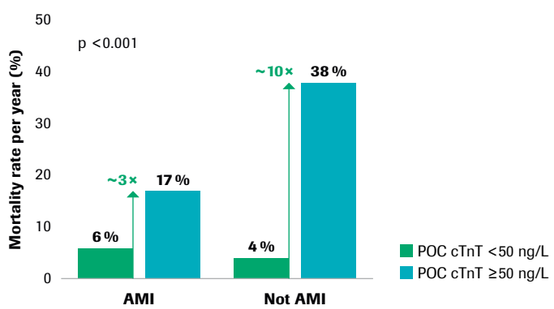


Use POC cTnT ≥ 50 ng/L to identify patients with suspected AMI at high risk of mortality

In the preHAP study, patients at the pre-hospital stage with suspected AMI and POC cTnT ≥ 50 ng/L:[11]

- Had 3 –10 × higher long-term mortality risk, irrespective of AMI[11]
- Required direct delivery to coronary intensive care or cath lab for medical investigation[11]

Long-term mortality risk of patients with suspected AMI[11]



Triage patients faster

ESC guidelines recommend an early invasive strategy (within 24 hours) for patients with high-risk NSTEMI.[10]

POC cTnT ≥ 50 ng/L ensures quick and adequate triage of those high-risk patients in pre-hospital and emergency department settings.[5,11]

In the STEMI I study, patients with POC cTnT ≥ 50 ng/L, in the pre-hospital phase or at hospital admission, and subsequent triage as STEMI-like, were associated with earlier revascularization and shorter hospital stay.[28]

The troponin values have to be used in conjunction with full clinical assessment including ECG and clinical symptoms.
NSTEMI: non-ST-segment elevation myocardial infarction, STEMI: ST-elevation myocardial infarction POC cTnT: POC Troponin T

How the cobas h 232 POC system works

Rapid and easy determination of cardiac biomarkers

Ready to use

- No sample preparation[2]
- No calibration (automatic)[2]
- No warm up[2]

Test in 3 steps

1. Insert test strip

2. Apply sample
of 150 µL heparinized whole blood using the Roche cardiac pipette

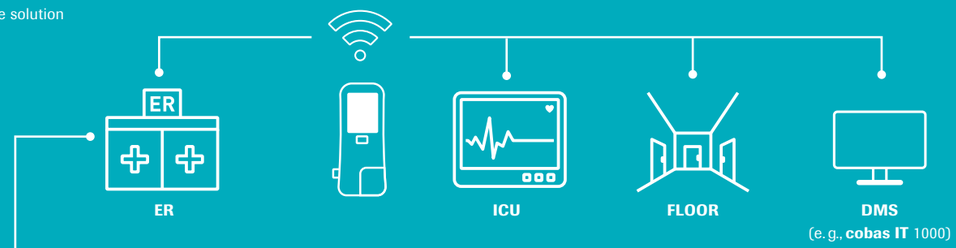
8–12 minutes

3. Read result

Share results in seconds with the multidisciplinary care team

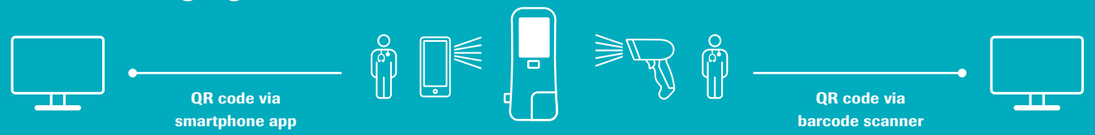
Use WiFi to provide real time results transmission anywhere in the hospital to ER, ICU, Floor and data management systems (DMS).[2]

Hospital
Via custom app or software solution



Use a QR code via the custom app or the barcode scanner to share results pre-hospital with the healthcare team.[2]

Pre-hospital



Access controlled[2]

- Operator identification ensures use is restricted to authorized staff
- Quality control lockout

Error reduction[2]

- Patient and user identification ensures correct documentation of test results
- Bar code scanner helps avoid manual errors

Standardized POC/laboratory test results[1,13]

- More certainty in test results and cut-off values
- Complete follow-up throughout patient journey

Ensuring more confidence every step of the way

Product specifications

Supported assays & controls

Parameter	Test	Supported units
Troponin T	Roche CARDIAC T Quantitative REF 04877772 190 Roche CARDIAC POC Troponin T REF 07007302 190	ng/L, pg/mL, ng/mL, µg/L
NT-proBNP	Roche CARDIAC proBNP+ REF 05533643 190	pg/mL
D-dimer	Roche CARDIAC D-Dimer REF 04877802 190	µg/mL, ng/mL, mg/L, µg/L
Myoglobin	Roche CARDIAC M REF 04877799 190	ng/mL
CK-MB	Roche CARDIAC CK-MB REF 04877900 190	ng/mL
Controls	Roche CARDIAC control for all parameters above. Roche CARDIAC IQC for checking the performance of the meter's optical system	

Sample material

Sample type	Heparinized venous whole blood
Sample size	150 µL

Operating conditions

Temperature range	18 to 32 °C
Relative humidity	10 – 85 % (no condensation)
Maximum altitude	4,300 m

Storage and transport conditions

Temperature range	–25 to 70 °C
Relative humidity	10 – 85 % (no condensation)

CK-MB, Creatine kinase-myocardial band; NT-proBNP: N-terminal natriuretic peptide fragment; POC, Point of Care.

Technical data

Screen	Color touchscreen
Memory	2,000 patient test results 500 QC test results 200 IQC test results 4,000 patient list entries 5,000 operator list entries
Data transfer via	QR code, WiFi, USB (handheld base unit and computer are required)
Interface	Infrared interface, LED/IRED class 1
Supported communication interfaces	IR-printers, POCT1-A communication via docking station, POCT1-A communication via WiFi, QR Code
Supported barcodes	Code 128, Code 39, Code 93, EAN 13, Interleaved 2/5, Codabar, GS1 DataBar Limited, QR Code, DataMatrix, PDF417, Aztec
Power adapter	Input: 100 – 240 V AC / 50 – 60 Hz / 400 – 150 mA, Output: 12 V DC / 1.50 A
Battery pack	Universal battery pack (Material order no.: REF 06869904001)
Battery operation	Meter switches off after auto-off-timer is elapsed (default 5 min) or pressing On/Off-button
Standby mode with external power supply	Meter automatically switches to ‘standby’ mode after 10 minutes of inactivity or by pressing On/Off-button
Start-up time	Less than 20 seconds (for new start) and 1 second (from standby mode)
Measurement time	8 to 12 minutes (depends on test parameter)
Number of tests with fully charged battery	Approx. 10 tests
Automatic power-off	Programmable 1…60 minutes
Dimensions	244 × 105 × 51 mm
Weight	526 g incl. battery pack and scanner

Material order no.

REF 04901126 190
With QR code,
no barcode scanner and no WiFi

REF 04901142 190
With integrated WiFi,
barcode scanner and QR code